NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for *Register* publication and the agency decides to make substantial changes to the rule after it is proposed, the agency must prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office, and the Secretary of State shall publish the Notice under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.). Publication of the Notice of Supplemental Proposed Rulemaking shall appear in the *Register* before holding any oral proceedings (A.R.S. § 41-1022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

Editor's Note: The following Notice of Supplemental Proposed Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 3286.) The Governor's Office authorized the notice to proceed through the rulemaking process on April 2, 2013.

[R13-177]

PREAMBLE

1. Citations to the agency's Notice of Rulemaking Docket Opening, the Notice of Proposed Rulemaking, and any other Notices of Supplemental Proposed Rulemaking (if applicable) as published in the *Register* as specified in R1-1-409(A). A list of any other related notices published in the *Register* to include those as specified in R1-1-409(A):

Notice of Rulemaking Docket Opening: 19 A.A.R. 895, April 26, 2013

Notice of Proposed Rulemaking: 19 A.A.R. 1475, June 7, 2013

2. Articles, Parts, or Sections Affected (as applicable) — **Rulemaking Action**

R12-1-611.01	New Section
R12-1-611.02	New Section

3. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 30-654(B)(5)

Implementing statutes: A.R.S. §§ 30-651, 30-654, 30-657, 30-671, 30-672, 30-673, 30-681, 30-687, 30-688, and 30-689

4. The agency's contact person who can answer questions about the rulemaking:

Name:	Jerry W. Perkins
Address:	Radiation Regulatory Agency 4814 S. 40th St. Phoenix, AZ 85040
Telephone:	(602) 255-4845 ext. 272
Fax:	(602) 437-0705
E-mail:	jperkins@azrra.gov
Website:	www.azrra.gov

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

This rulemaking adds rules to ensure that Arizona radiation compliance addresses recent safety issues related to emergent technical advances in equipment.

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

7. An explanation of the substantial change which resulted in the supplemental notice:

The Agency is seeking additional comments for consideration to address concerns raised after the close of record for these rules. A modification from "two days" to "prior to next patient use" was made to the calibration requirement listed in R-12-1-611.01(K)(5)(b) based upon comments made during the first hearing. In addition, changes since the notice of proposed rulemaking include a clarification that either a qualified physicist or an authorized user must be present at the time of treatment. In addition a clarification of the information for the reporting criteria required for misadministration related to x-ray therapy is included.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

9. The preliminary summary of the economic, small business, and consumer impact:

There is little or minimal economic impact from any of the proposed rules in this rulemaking. Currently, all registrants pay an annual fee which covers the administrative cost and inspection fees for each facility registration number. This package has no fee increase or new requirements that would markedly change the way businesses operate with radiation safety concerns in mind. The amendments in this rulemaking address recent safety issues related to emergent technical advances in equipment.

10. The agency's contact person who can answer questions about the economic, small business and consumer impact statement:

Name:	Jerry W. Perkins
Address:	Radiation Regulatory Agency 4814 S. 40th St. Phoenix, AZ 85040
Telephone:	(602) 255-4845 ext. 272
Fax:	(602) 437-0705
E-mail:	jperkins@azrra.gov
Website:	www.azrra.gov

11. The time, place, and nature of the proceedings to make, amend, repeal or renumber the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the supplemental proposed rule:

An oral proceeding at the Agency will be scheduled for 9:00 am on November 21, 2013 at 4814 S. 40th St., Phoenix, AZ. A person may also submit written comments concerning the proposed rules by submitting them no later than 5:00 pm November 21, 2013, to the following person:

Name:	Aubrey V. Godwin, Director
Location:	Radiation Regulatory Agency 4814 S. 40th St. Phoenix, AZ 85040
Telephone:	(602) 255-4845
Fax:	(602) 437-0705

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The Agency believes that it is exempt from A.R.S. §§ 41-1037 due to paragraph (A)(2) as the issuance of an alternative type of permit is authorized under the statutory requirement of A.R.S. §§ 30-672 to protect the public health and safety.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

The rule amendments are compatible with existing federal regulations and are not more stringent in sections that have a federal equivalent.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No analysis has been submitted.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

Not applicable.

14. The full text of the rule follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 6. USE OF X-RAYS IN THE HEALING ARTS

Section
R12-1-611.01. Electronic Brachytherapy
R12-1-611.02. Other Use of Electronically-Produced Radiation to Deliver Superficial Therapeutic Radiation Dosage

ARTICLE 6. USE OF X-RAYS IN THE HEALING ARTS

R12-1-611.01. Electronic Brachytherapy

A. Electronic brachytherapy devices shall be subject to the requirements of this Section, and shall be exempt from the requirements of R12-1-611.
1. An electronic brachytherapy device that does not meet the requirements of this Section shall not be used for irradiation of patients; and
2. An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA), unless participating in a research study approved by the registrant's Institutional Review Board (IRB).

B. Each facility location authorized to use an electronic brachytherapy device in accordance with this Section shall possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall include a portable survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument or instruments shall be operable and calibrated before first use, at intervals not to exceed 12 months, and after survey instrument repairs.

C. Facility Design Requirements for Electronic Brachytherapy Devices. In addition to shielding adequate to meet requirements of R12-1-603(C), the treatment room shall meet the following design requirements:
1. If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.
2. Access to the treatment room shall be controlled by a door at each entrance.
3. Each treatment room shall have provisions to permit continuous oral communication and visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed.
4. For electronic brachytherapy devices capable of operating below 150 kVp, radiation shielding for the staff in the treatment room shall be available, either as a portable shield and/or as localized shielded material around the treatment site.
5. For electronic brachytherapy devices capable of operating at or greater than 150 kVp, the facility must meet the requirements of R12-1-611(B)(4).

D. Control Panel Functions. The control panel, in addition to the displays required by other provisions in this Section, shall:
1. Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;
2. Provide an indication of whether x-rays are being produced;
3. Provide a means for indicating electronic brachytherapy source potential and current;
4. Provide the means for terminating an exposure at any time; and
5. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

E. Timer. A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.
1. A timer shall be provided at the treatment control panel. The timer shall indicate the planned setting and the time elapsed or remaining;
2. The timer shall not permit an exposure if set at zero;
3. The timer shall be a cumulative device that activates with an indication of "BEAM-ON" that retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;
4. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.
5. The timer shall permit setting of exposure times as short as 0.1 second; and
6. The timer shall be accurate to within one percent of the selected value or 0.1 second, whichever is greater.

F. Qualified Medical Physicist Support.
1. The services of a Qualified Medical Physicist shall be required in facilities having electronic brachytherapy devices. The Qualified Medical Physicist shall be responsible for:

a. Evaluation of the output from the electronic brachytherapy source;
b. Generation of the necessary dosimetric information;
c. Supervision and review of treatment calculations prior to initial treatment of any treatment site;
d. Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in subsection (J);
e. Consultation with the authorized user in treatment planning, as needed; and
f. Performing calculations/assessments regarding patient treatments that may constitute a medical event.

2. If the Qualified Medical Physicist is not a full-time employee of the registrant, then the operating procedures required by subsection H shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

G. Operating Procedures.

1. Only individuals approved by the authorized user, Radiation Safety Officer, or Qualified Medical Physicist shall be present in the treatment room during treatment;
2. Electronic brachytherapy devices shall not be made available for medical use unless the requirements of subsections (A), (H), and (J) have been met;
3. The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;
4. During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent entering persons from unshielded exposure from the treatment beam;
5. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;
6. Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:
   a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and
   b. The names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.
7. A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console;
8. Instructions shall be maintained with the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally; and
9. The Radiation Safety Officer, or the Radiation Safety Officer's designee, and an authorized user shall be notified immediately if the patient has a medical emergency, suffers injury or dies. The Radiation Safety Officer or the Qualified Medical Physicist shall inform the manufacturer of the event.

H. Safety Precautions for Electronic Brachytherapy Devices.

1. An individual other than the person being treated shall wear personnel monitoring devices;
2. An authorized user and a Qualified Medical Physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;
3. After the first treatment one of the following individuals shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device:
   i. A Qualified Medical Physicist, or
   ii. An authorized user, or
   iii. A certified therapy technologist (CTT) by the Arizona Medical Radiological Technology Board of Examiners, under the direct supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device;
4. When shielding is required by subsection (C)(4), surveys shall be conducted to ensure that the requirements of R12-1-408, R12-1-414, and R12-1-416 are met. Alternatively, a Qualified Medical Physicist shall designate shield locations sufficient to meet the requirements of R12-1-603(C) and R12-1-607(C) for any individual, other than the patient, in the treatment room; and
5. All personnel in the treatment room are required to remain behind shielding during treatment. A Qualified Medical Physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

I. Electronic Brachytherapy Source Calibration Measurements.

1. Calibration of the electronic brachytherapy source output shall be performed by, or under the direct supervision of, a Qualified Medical Physicist. If the control console is integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during electronic brachytherapy device operation.
2. Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

3. Calibration of the electronic brachytherapy source output shall utilize a dosimetry system appropriate for the energy output of the unit and calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration;
4. Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:
   a. The output within two percent of the expected value, if applicable, or determination of the output if there is no expected value;
   b. Timer accuracy and linearity over the typical range of use;
   c. Proper operation of back-up exposure control devices;
   d. Evaluation that the relative dose distribution about the source is within five percent of that expected; and
   e. Source positioning accuracy to within one millimeter within the applicator;
5. Calibration of the x-ray source output required shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.
6. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for it's electronic brachytherapy source; the model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and the name and signature of the Qualified Medical Physicist responsible for performing the calibration.

J. Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices.

1. Quality assurance checks shall be performed on each electronic brachytherapy device:
   a. At the beginning of each day of use;
   b. Each time the device is moved to a new room or site; and
   c. After each x-ray tube installation.
2. The registrant shall perform periodic quality assurance checks required in accordance with procedures established by the Qualified Medical Physicist;
3. To satisfy the requirements of this subsection, radiation output quality assurance checks shall include at a minimum:
   a. Verification that output of the electronic brachytherapy source falls within three percent of expected values, as appropriate for the device, as determined by:
      i. Output as a function of time, or
      ii. Output as a function of setting on a monitor chamber.
   b. Verification of the consistency of the dose distribution to within three percent (or the manufactures or Qualified Physicists documented recommendation not to exceed five percent), observed at the source calibration required by R12-1-611.01(H); and
   c. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one millimeter; and
4. The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in this Section to make the quality assurance checks required in R12-1-611.01(I)(3);
5. The registrant shall review the results of each radiation output quality assurance check to ensure that:
   a. An authorized user and Qualified Medical Physicist is immediately notified if any parameter is not within its acceptable tolerance, and the electronic brachytherapy device is not used until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;
   b. If all radiation output quality assurance check parameters appear to be within their acceptable range, the acceptable quality assurance check shall be reviewed and signed by either the authorized user or Qualified Medical Physicist prior to the next patient use of the unit. In addition, the Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.
6. To satisfy the requirements of R12-1-611.01(J)(1), safety device quality assurance checks shall, at a minimum, assure:
   a. Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;
   b. Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;
   c. Proper operation of radiation monitors, if applicable;
   d. The integrity of all cables, catheters or parts of the device that carry high voltages; and
   e. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.
7. If the results of the safety device quality assurance checks required in R12-1-611.01(J)(6) indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

8. The registrant shall maintain a record of each quality assurance check required by R12-1-611.01 in a legible form for three years.
   a. The record shall include the date of the quality assurance check; the manufacturer's name, model number and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check and the name and signature of the Qualified Medical Physicist who reviewed the quality assurance check;
   b. For radiation output quality assurance checks required by R12-1-611.01(J)(3), the record shall also include the unique identifier for the electronic brachytherapy source and the manufacturer's name; model number and serial number for the instrument or instruments used to measure the radiation output of the electronic brachytherapy device.

K. Therapy-related Computer Systems. The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.
1. Acceptance testing shall be performed by, or under the direct supervision of a Qualified Medical Physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:
   a. The source-specific input parameters required by the dose calculation algorithm;
   b. The accuracy of dose, dwell time, and treatment time calculations at representative points;
   c. The accuracy of isodose plots and graphic displays;
   d. The accuracy of the software used to determine radiation source positions from radiographic images; and
   e. If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.
2. The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.
3. Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated for correctness and approved by the authorized user and the Qualified Medical Physicist through means independent of that used for the determination of the parameters.

L. Training for e-brachytherapy Authorized Users.
1. The registrant for any therapeutic radiation machine subject to this Section shall require the authorized user to be a physician who is certified in:
   a. Radiation oncology or therapeutic radiology by the American Board of Radiology or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or
   b. Radiation oncology by the American Osteopathic Board of Radiology; or
   c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
   d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
2. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.
   a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:
      i. Radiation physics and instrumentation;
      ii. Radiation protection;
      iii. Mathematics pertaining to the use and measurement of ionization radiation; and
      iv. Radiation biology.
   b. To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:
      i. Review of the full calibration measurements and periodic quality assurance checks;
      ii. Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
      iii. Using administrative controls to prevent medical events as described in R12-1-444;
      iv. Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
      v. Checking and using radiation survey meters.
   c. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:
      i. Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

ii. Selecting proper dose and how it is to be administered;
iii. Calculating the therapeutic radiation machine doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and
iv. Post-administration follow-up and review of case histories.

3. Notwithstanding the requirements of this subsection, the registrant for any therapeutic radiation machine subject to this Section may also submit the training of the prospective authorized user physician for Agency review on a case-by-case basis if the training includes substantially equivalent training as that listed in subsection (2) and the training includes dosimetry calculation training and experience.
4. A physician shall not act as an authorized user until such time as said physician's training has been reviewed and approved by the Agency.

M. Training for Qualified Medical Physicist. The registrant for any therapeutic radiation machine subject to this Section shall require the Qualified Medical Physicist to:

1. Be certified with the Agency, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and
2. Be certified by the American Board of Radiology in:
   a. Therapeutic radiological physics; or
   b. Roentgen-ray and gamma-ray physics; or
   c. X-ray and radium physics; or
   d. Radiological physics; or
3. Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or
4. Be certified by the Canadian College of Medical Physics; or
5. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, and have completed one year of full time training in medical physics and an additional year of full time work experience under the supervision of a Qualified Medical Physicist at a medical institution. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to one MV/one MeV). To meet this requirement, the individual shall have performed the tasks listed in this Section under the supervision of a Qualified Medical Physicist during the year of work experience.

N. Qualifications of Operators. Individuals who will be operating a therapeutic radiation machine for medical use shall be certified by the Agency as a CTT by the Arizona Medical Radiological Technology Board of Examiners.

O. Additional training requirements.

1. A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in R12-1-611.01(G). If the interval between patients exceeds one year, retraining of the individuals shall be provided.
2. In addition to the requirements of R12-1-611.01(L) for therapeutic radiation machine authorized users and R12-1-611.01(M) for Qualified Medical Physicists, these individuals shall also receive device-specific instruction initially from the manufacturer, and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer’s training protocol shall be followed. The training shall include, but not be limited to:
   a. Device-specific radiation safety requirements;
   b. Device operation;
   c. Clinical use for the types of use approved by the FDA;
   d. Emergency procedures, including an emergency drill; and
   e. The registrant’s Quality Assurance Program.
3. A registrant shall retain a record of individuals receiving manufacturers instruction for three years The record shall include a list of the topics covered, the date of the instruction, the name or names of the attendee or attendees, and the name or names of the individual or individuals who provided the instruction.

P. Mobile Electronic Brachytherapy Service. A registrant providing mobile electronic brachytherapy service shall, at a minimum:

1. Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive;
2. Account for the electronic brachytherapy x-ray tube in the electronic brachytherapy device before departure from the client’s address; and
3. Perform, at each location on each day of use, all of the required quality assurance checks specified in this Section to assure proper operation of the device.

Q. Misadministration’s shall be reported to the Agency. For purposes of this Section “misadministration” means:

1. A therapeutic radiation dose from a machine:
   a. Delivered to the wrong patient;

b. Delivered using the wrong mode of treatment;
c. Delivered to the wrong treatment site; or
d. Delivered in one week to the correct patient, using the correct mode, to the correct therapy site, but greater than 130 percent of the prescribed weekly dose; or

R. A therapeutic radiation dose from a machine with errors in the calibration, time of exposure, or treatment geometry that result in a calculated total treatment dose differing from the final, prescribed total treatment dose by more than 20 percent, except for treatments given in 1 to 3 fractions, in which case a difference of more than 10 percent constitutes a misadministration.

S. Reports of therapy misadministration:

1. Within 24 hours after discovery of a misadministration, a registrant shall notify the Agency by telephone by speaking to an Agency staff member. The registrant shall also notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician personally informs the registrant either that he or she will inform the patient, or that in his or her medical judgment, telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. If the Agency staff member, referring physician, or the patient's responsible relative or guardian cannot be reached within 24 hours, the registrant shall notify them as soon as practicable. The registrant shall not delay medical care for the patient because of notification problems.
2. Within 15 days following the verbal notification to the Agency, the registrant shall report, in writing, to the Agency and individuals notified under subsection (S)(1). The written report shall include the registrant's name, the referring physician's name, a brief description of the event, the effect on the patient, the action taken to prevent recurrence, whether the registrant informed the patient or the patient's responsible relative or guardian, and if not, why not. The report shall not include the patient's name or other information that could lead to identification of the patient.
3. Each registrant shall maintain records of all misadministrations for Agency inspection. The records shall:
   a. Contain the names of all individuals involved in the event, including:
      i. The physician,
      ii. The allied health personnel,
      iii. The patient,
      iv. The patient's referring physician,
      v. The patient's identification number if one has been assigned,
      vi. A brief description of the event,
      vii. The effect on the patient, and
      viii. The action taken to prevent recurrence.
   b. Be maintained for three years beyond the termination date of the affected registration.

R12-1-611.02. Other Use of Electronically-Produced Radiation to Deliver Superficial Therapeutic Radiation Dosage

A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

1. The applicant or registrant has, at a minimum, provided the Agency with:
   a. A detailed description of the device and its intended application or applications;
   b. Facility design requirements, including shielding and access control;
   c. Documentation of appropriate training for authorized user physician or physicians and qualified medical physicist or physicists;
   d. Methodology for measurement of dosages to be administered to patients or human research subjects;
   e. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;
   f. Radiation safety precautions and instructions; and
   g. Other information requested by the Agency in its review of the application; and
2. The applicant or registrant has received written approval from the Agency to utilize the device in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the device; and
3. Submitted the application information and forms required by Article 2.
4. In addition to the requirements of this Section, a registrant using a device for x-ray radiation therapy shall meet the requirements of R12-1-611.01(Q), (R), and (S).